

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

W. R. GRACE & CO.-CONN.,

Plaintiff,

v.

ELYSIUM HEALTH, INC.,

Defendant.

C.A. No. 20-1098-CFC-JLH

**FILED UNDER SEAL**

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**PLAINTIFF'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO  
DISMISS DEFENDANT'S INEQUITABLE CONDUCT COUNTERCLAIMS  
AND STRIKE RELATED AFFIRMATIVE DEFENSE**

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To support its serious allegations, Elysium was required to plead facts from which the Court could reasonably infer that a specific individual knew that the claimed crystalline forms—identified by analytical methods—were commercially sold before the critical dates. Elysium pleads no such facts. In fact, it *cites no analytical data whatsoever*. For this and the other reasons discussed below, the Court should grant Grace’s motion.

# **I. Elysium Fails to Plead Materiality**

## **A. Grace Applies the Correct Legal Standard**

Grace does not “conflate” *Therasense* with *Exergen*. See Elysium’s Opposition, D.I. 152 (“Opp.”) at 6-7. Rather, Grace points out that *Therasense* *did* impact the pleading standards by requiring one to “allege facts allowing for the reasonable inference of ‘*but-for*’ materiality” – that is, that the PTO would not have allowed a claim to issue. *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. CIV.A. 09-955-LPS, 2012 WL 600715, at \*6 (D. Del. Feb. 3, 2012) (emphasis added).

## **B. Elysium Did Not Plead that Grace Sold the Claimed Crystalline Forms**

Elysium distances itself from its initial allegation: [REDACTED]

[REDACTED] As Grace explained, [REDACTED]  
[REDACTED] the asserted claims are directed to particular crystalline forms identified by analytical data, [REDACTED]

[REDACTED]. Elysium's [REDACTED] allegations do not permit a reasonable inference that the material was Form I or II.

Elysium thus shifts its focus, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Moreover, Elysium's allegation that [REDACTED] is, at best, an unsupported conclusion and unwarranted inferences, which the Court need not take as true. *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (holding that plaintiff's allegation that it was defendant's competitor was "belied by both the remaining factual allegations and the law"). [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**C. Elysium's New Extrinsic Evidence Cannot Save Its Pleading**

Attempting to salvage its *second* deficient inequitable conduct pleading, Elysium's opposition cites new documents not identified in its pleading. The Court should not consider them. *Invista N. Am. S.a.r.l. v. M&G USA Corp.*, No. 11-1007-SLR-CJB, 2013 WL 12304544, at \*3 (D. Del. May 3, 2013). However, these documents do not impact the outcome. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**D. Elysium Applied the Wrong Legal Standard for Materiality**

Elysium’s failure to apply the correct materiality standard has nothing to do with the preponderance of the evidence standard applied by the USPTO, and its arguments miss the mark entirely. (*See Opp.* at 15-16.) Elysium pleads that if the purported sales had been disclosed, “the patent examiner would have ***rejected*** the pending claims requiring Grace to characterize the crystal structure . . .” (Ans. ¶76; *see also id.* ¶73) (emphasis added). But Elysium was required to allege that the PTO would not have ***allowed*** a claim had it been aware of the undisclosed information, not that the PTO would have ***rejected*** a claim that could have subsequently been overcome. *Therasense*, 649 F.3d at 1291(*overruling Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed.Cir.1984)). Elysium has simply not plead “but for” materiality.

Elysium points to conclusory statements that “the on-sale bar (35 U.S.C. § 102) would render claims covering the crystalline nicotinamide riboside chloride

offered for sale and sold invalid” (Ans. ¶73) and that Grace allegedly withheld information to “obtain patent claims that otherwise would not have been allowed” (Ans. ¶76). But “[a] pleading that simply avers the substantive elements of inequitable conduct without setting forth the particularized factual bases for the allegation” is plainly insufficient. *Exergen*, 575 F.3d at 1326-27. Elysium had to plead *facts* from which the Court could “reasonably draw the inference that the patents *would not have issued* but for the alleged omission.” *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 383 (D. Del. 2012) (emphasis added). Elysium failed to allege that a specified patent claim would not have issued but for information withheld from the PTO.

## **II. Elysium Did Not Tie Its Allegations to Claims and Limitations**

Elysium merely alleges that Forms I and II “as claimed” in the patents-in-suit were sold prior to the critical dates. But the Court’s claim construction requires that the claimed forms be “identified by one or more of the analytical methods described in the specification.” D.I. 109. Elysium made no attempt to tie its allegations to those analytical methods, as required by *Exergen*. 575 F.3d at 1329. *Exergen* requires the pleading to identify which claim limitations the withheld references are relevant to, and where in the withheld information the material information is found. *Id.*



Elysium failed to tie its allegations to the claim limitations notwithstanding being put on notice that the Court expected Elysium to do so. See D.I. 120 at 71:7-12; 73:13-22; 82:19-22. This is despite first raising inequitable conduct more than six months ago. For this reason alone, Elysium's amended pleading should be rejected. *See Milwaukee Elec. Tool Corp. v. Hitachi Koki Co.*, No. 09-C-948, 2012 WL 1952977, at \*7 (E.D. Wis. May 29, 2012) (holding that alleging that "each of the prior art references...anticipates or renders obvious the claims of the...patents" was insufficient); *Exergen* 575 F.3d at 1329.

Elysium's cited cases are distinguishable. In *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, allowance hinged on affirmative statements made by co-inventor Roberts, which stated that Quest only used and sold the "Original" system which did not perform the relevant claim limitations (e.g., 3D mapping), despite contradictory evidence of prior sales of the "Improved" system and a published article by Roberts describing such limitations. No. CV 14-1482-SLR, 2015 WL 4477700, at \*4 (D. Del. July 22, 2015) (see D.I. 268). Here, affirmative statements are not at issue and, moreover, Elysium fails to point to any evidence of withheld information that shows any prior sales meet the claim limitations of one or more patent claims. In *Sysmex Corp. v. Beckman Coulter, Inc.*, the Court had initially granted Sysmex's motion to dismiss because BCI (1) failed to plausibly allege enough facts and inappropriately tried to amend its counterclaim through its briefing,

and (2) failed to plead any facts that: “(1) identify what claim limitations are disclosed in the allegedly withheld prior art references (and where those limitations are disclosed); and (2) explain which of those limitations are not found in the prior art that was before the Examiner (i.e., explaining why the references are material and not cumulative of information already in the record).” No. CV 19-1642-JFB-CJB, 2022 WL 1503987 (D. Del. May 6, 2022) (D.I. 250). The Court ultimately denied the motion only after BCI identified the particular claim limitation at issue. *Id.*, at D.I. 433. Here, Elysium has not done so.

### III. **Elysium Does Not Plead that Any Individual Knew of the Alleged Sales, Knew of their Materiality, and Had Deceptive Intent**

It is indisputable that *Exergen* requires pleading “sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, **and** (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1328-29 (emphasis added). Elysium must plead facts permitting a reasonable inference that a ***specific individual*** “knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *See Therasense.*, 649 F.3d at 1290. Elysium fails to do so.

The fact that Elysium did not list “Grace” or use the conjunction “or” in its list of accused individuals does not make its imprecise references to “other inventors” and unnamed “other individuals at Grace” proper. As discussed in

Grace's opening, courts routinely dismiss inequitable conduct claims containing similar vague allegations. *See, e.g., Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013).

Indeed, Elysium's pleading attempts to cobble together an inequitable conduct claim by combining several different individuals' purported knowledge. Regarding Brett Reynolds (not an inventor), [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But Elysium did not plead this or any underlying facts to support it. (*See* Ans. ¶¶45, 68-70.) [REDACTED]

[REDACTED]

[REDACTED] This is akin to Grace alleging infringement by pleading Elysium sold NRCl, rather than the specific claimed crystalline forms. It would not meet the lower pleading standards of Rule 8, let alone the more stringent pleading standard for inequitable conduct.

Moreover, "one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material information contained in that reference." *Exergen*, 575 F.3d at 1330. [REDACTED]

[REDACTED]

[REDACTED]

For Erik Carlson, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] None of this permits an inference that Mr. Carlson knew that Grace made commercial sales of the claimed crystalline forms to ChromaDex before the relevant critical dates.

And Elysium pleads no facts whatsoever permitting an inference that inventors Standen, Morrill, and Osuna knew that Grace sold or offered NRCl for sale to ChromaDex before the relevant critical dates *and* that this NRCl was Form I and/or Form II. Mr. Osuna's name does not appear in Elysium's inequitable conduct allegations [REDACTED]

[REDACTED]

Elysium's cited cases are inapposite. *Sanders v. The Mosaic Co.* concerned a pleading that alleged that the applicant failed to disclose its affiliation with an expert based on the expert's omission of references co-written by the expert and the applicant from the expert's CV. 418 F. App'x 914, 919 (Fed. Cir. 2011). It was undisputed that the applicant co-wrote the omitted references. As such, "the court

could reasonably infer both knowledge and intent to deceive the Patent Office.” *Id.* *Kaszuba v. Iancu* concerned a trademark cancellation proceeding, not inequitable conduct claims. 823 F. App’x 973 (Fed. Cir. 2020). And the court in that case concluded that the petitioner adequately pled that the trademark applicant knowingly misrepresented that his beer was being sold in commerce and had submitted false label specimens because it pled facts showing that the applicant was required to register the beer label under federal regulations in order to sell it and that no such label was ever registered. *Id.* Here, Elysium has not alleged facts from which the Court can reasonably infer that a singular individual knew that Grace offered or sold the claimed Form I and/or Form II NRCI to ChromaDex before the relevant critical dates.

Finally, that “no depositions were taken when Elysium filed its amended pleading” is irrelevant and does not lower the bar. (*See Opp.* at 17.) Elysium represented to Grace and the Court that it had a “Rule 11 basis” to plead inequitable conduct and did not suggest it needed further discovery to plead its case. (*See D.I.* 120 at 81:6.)

#### **IV. Grace Did Not Spoliate Evidence**

Elysium’s unfounded spoliation allegations cannot make up for its failure to adequately plead inequitable conduct. Elysium admits that it has no basis to allege that Grace destroyed evidence. (*See Opp.* at 22.) Elysium also concedes that

spoliation is irrelevant as it is “not an inequitable conduct element.” (*Id.* at 1.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dated: June 20, 2022

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**CERTIFICATE OF COMPLIANCE WITH**  
**TYPE VOLUME LIMITATIONS**

I certify that the foregoing brief satisfies the type volume limitations specified by Local Rule 7.1.3(4), as modified by Judge Colm F. Connolly's "Standing Order Regarding Briefing in All Cases." I certify that the text of this brief is presented in 14-point Times New Roman font and that, based upon the word count of the word-processing system used to prepare this brief, the number of words contained in the text of this brief is 2439.

/s/ Daniel A. O'Brien  
Daniel A. O'Brien (No. 4897)

# EXHIBIT A



**REDACTED IN  
ITS ENTIRETY**

**CERTIFICATE OF SERVICE**

I, Daniel A. O'Brien, hereby certify that on this 30th day of June, 2022, a copy of the foregoing document was electronically filed with the court and served via CM/ECF, on parties with counsel of record identified on the Court's docket.

/s/ Daniel A. O'Brien

Daniel A. O'Brien (No. 4897)